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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,718	03/21/2001	Paul Schimmel	TSRI 817.0	3346

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/813,718

Applicant(s)

SCHIMMEL ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-48 is/are pending in the application.
- 4a) Of the above claim(s) 9-35 and 38-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, and 36-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

***Response to Amendment***

The Amendment filed February 03, 2003 (Paper No. 10) in response to the Office Action of November 01, 2002 is acknowledged and has been entered.

Claim 2 was cancelled.

Claims 1, and 3-48 are pending.

Claims 9-35, and 38-48 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1, 3-8, and 36-37 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained**

Claims 1, 6 and 37 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for the reasons of record in Paper No. 9, pages 6-9.

As a first point, applicants argue (Paper No. 10, page 6) that since claim 2 was not included in the original rejection (and has now been incorporated into claim 1), the rejection should be withdrawn with respect to Claim 1. This argument has been considered but is not found persuasive. Claim 6 is directly dependent from Claim 1 and thus the embodiment of

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Claim 2 was not previously considered. Secondly, the amendment to Claim 1 does not obviate the scope of enablement with regards to "fragments thereof" for the reasons set forth below.

Applicants argue (Paper No. 10, page 6) that one of ordinary skill in the art at the time the invention was filed would have been able to practice the full scope of the claimed invention. With regards to fragments, applicants point to the specification on pages 53 and 59. Applicants argue that the presence of a contiguous DLT tripeptide fragment can be determined by sequencing the fragment and that the specification is replete with detailed descriptions for assaying vascular endothelial cell function activity of such fragments. These arguments have been considered but are not found persuasive for the reasons of record. The claims remain broadly drawn to any and all isolated polypeptides "comprising" a truncated tryptophanyl-tRNA synthetase polypeptide comprising a Rossmann fold nucleotide binding domain which is further limited to a size of at least about 46 kilodaltons. The subject matter of claims 6 and 37 broadly encompasses a *world* of amino acid fragments so long as they comprise the tripeptide DLT and so long as they are capable of regulating vascular endothelial cell growth. As set forth in the previous rejection, applicant has not enabled all of these types of modified proteins because it has not been shown that these modified proteins are capable of functioning as that which is being disclosed. Furthermore, protease cleavage of full-length TrpRS (Example 11, page 59) only served to identify two biologically active cleavage products, a major fragment of 47 kDa and a minor fragment of 44 kDa; the isolation of which does not reasonably extrapolate to any and all fragments thereof comprising the amino acid sequence of Asp-Leu-Thr. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

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Claims 1, 4-8, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleckner *et al.* (Proc.Natl.Acad.Sci. Vol. 88, pages 11520-11524, 1991) for the reasons of record in Paper No. 9, pages 10-11.

Applicants argue (Paper No. 10, pages 6-7) that Fleckner *et al.* only discloses the full length tryptophanyl-tRNA synthetase which has a molecular weight of approximately 54 kilodaltons whereas the claims are directed to truncated tryptophanyl-tRNA synthetase polypeptides. This argument has been considered but is not found persuasive. While the claims are directed to truncated tryptophanyl-tRNA synthetase polypeptides, the broadly claimed subject matter is actually drawn to an isolated polypeptide *comprising* a truncated tryptophanyl-tRNA synthetase polypeptide. Thus, due to the open language, the claims include amino acid additions to the carboxy and or amino terminals and thus broadly include full-length tryptophanyl-tRNA synthetase polypeptide. To clarify, this rejection can be obviated by amending the claim to read, "An isolated, truncated tryptophanyl-tRNA synthetase polypeptide..." Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1, 3-5, 7, 36 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lemaire *et al.* (Eur.J.Biochem. Vol. 51. No. 1, pages 237-52, 1975) for the reasons of record in Paper No. 9, pages 12-13.

Applicants argue that Lemaire *et al.* do not teach a truncated tryptophanyl-tRNA synthetase having a size of at least about 46 kilodaltons. This argument has been considered but is not found persuasive since the claimed truncated tryptophanyl-tRNA synthetase reads on the

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full-length protein for the reasons set forth above. Furthermore, claim language drawn to “relative to full length tryptophanyl-tRNA synthetase having a size of about 54 kilodaltons” is relative terminology and does not serve as an upper limitation to the claimed polypeptide. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained since Lemaire *et al.* teach an isolated mammalian polypeptide comprising a truncated tryptophanyl-tRNA synthetase polypeptide (TRS<sub>82</sub>) which has a size of at least about 46 kilodaltons wherein the truncated tRNA synthetase polypeptide has amino-terminal truncation.

**All other rejections and or objections are withdrawn in view of applicant’s amendments and arguments there to.**

No claim is allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.  
Examiner  
Art Unit 1642

GBN  
April 18, 2003

  
ANTHONY C. CAPUTA  
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